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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) PTB-4398-407 Confirmation No. 4380	
		Application Number	Filed
		10/523,607	March 10, 2005
		First Named Inventor BERTHON-JONES	
		Art Unit	Examiner
		3772	Brandon Lee Jackson

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ Applicant/Inventor

☐ Assignee of record of the entire interest. See 37 C.F.R. § 3.71. Statement under 37 C.F.R. § 3.73(b) is enclosed. (Form PTO/SB/96)

☒ Attorney or agent of record 38,009
(Reg. No.)

☐ Attorney or agent acting under 37CFR 1.34.
Registration number if acting under 37 C.F.R. § 1.34 _____

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Requester's telephone number

November 1, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.*

☒ *Total of 1 form/s are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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STATEMENT OF ARGUMENTS IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 24-51 were rejected under 35 U.S.C. §103(a) over Gradon (U.S. Pat. No. 6,615,834) in view of Garelick (U.S. Pat. No. 2,823,671). The Office Action includes the errors that follow:

Error #1 There is no motivation to combine Gradon and Garelick as suggested

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to have replaced the Gradon cushion to have a same cross sectional configuration as taught by Garelick, in order to comfortably seal the mask to the user's face. However, the mask of Gradon is already provided to be more comfortable for a user to wear than prior art masks. See col. 2, lines 57-61.

There is no evidence that applying the cushion configuration of Garelick to the Gradon mask would result in a more comfortable mask. It could be that Garelick's cushion, from 1958, would be less comfortable than the Gradon cushion. Especially as Garelick teaches a non-pressurized air-filter mask, there is no teaching that such a mask would have a predictable benefit. The Examiner fails to provide any reasoning as to how the comfort of the cushion of Gradon would be improved if the Gradon mask was modified as suggested. In any event, Gradon's mask likely is already designed to alleviate inordinate sealing forces applied to the nose, such that there would be nothing in Garelick to apply to Gradon. Stated differently, there are no apparent reasons related to comfort as to why Garelick's cushion configuration would be applied to Gradon's mask.

Moreover, the Gradon mask is a nasal only CPAP mask, including a flap-type seal that receives pressurized gas. In such a CPAP mask, it is important to maintain an effective pressure seal with the user so that the pressurized gas does not leak out. It is preferable for a CPAP mask to not interface with a user's chin, because the backwards pressure put on the chin by the mask and headgear tends to push back the user's lower jaw, closing the user's airways and making the CPAP treatment less effective (and/or requiring high pressures). It is also noted that the Gradon cushion includes the typical CPAP cushion that curls inward towards an interior of the mask, which helps to trap pressurized gas within the breathing chamber, thereby enhancing the seal.

In contrast, the Garelick mask is a full face respirator mask with a compression-type cushion that surrounds the user's mouth and nose, the cushion being configured to interface with the user's chin. See col. 3, lines 56-62. In fact, the seal in the chin area is made more

rigid such that the chin area takes on more of the forces required to support the mask on the user's head. See col. 3, line 40 through col. 4, line 15. This is undesirable for CPAP therapy and CPAP masks.

Moreover, in such a respirator mask, pressurized gas is not applied, and a "pressure seal" (as typically used in a CPAP mask) is not needed. Rather, in such compression-type seals, the sealing force is determined solely by the strap tension; pressurized gas (if any) plays no role in terms of sealing. Further, the Garelick cushion curls outward, which allows easier escape of air than an inwardly curling cushion such as the Gradon CPAP cushion.

It would not have been obvious for one of ordinary skill in the art to have applied the respirator cushion of Garelick, which includes an outwardly curling cushion and does not require a pressure seal, to the CPAP mask of Gradon that includes an inwardly curling cushion and requires a pressure seal. Further, the Garelick cushion configured to interface with the user's chin would be inappropriate for the nasal CPAP mask of Gradon.

Error #2 Neither Gradon nor Garelick teaches an inner leg extending in direction of airflow, the inner leg defining cushion opening, or the inner leg being smooth, continuous and uninterrupted (claims 24 and 38)

Even if Gradon and Garelick are combinable, which is not admitted, neither Gradon nor Garelick disclose or suggest: 1) a cushion, in cross section, having a generally U-shaped configuration defining a face contacting surface, an inner leg of the U-shaped configuration being proximal to the frame and an outer leg defining a distal end spaced away from the frame, the inner leg defining an opening in the cushion, the opening being adapted to receive pressurized gas from the CPAP device, wherein the U-shaped configuration includes a connecting portion between the inner leg and the outer leg that provides said face contacting surface, and the inner leg extends in a continuous, uninterrupted and smooth manner in a direction of flow of the pressurized gas through the opening, as recited in independent claim 24; or 2) a cushion having a generally U-shaped cross-sectional configuration, the cushion including an inner leg, an outer leg, and a face contacting surface formed between the inner leg and the outer leg, the inner leg defining an opening in the cushion, the opening adapted to receive pressurized gas from the CPAP device, wherein the inner leg extends in a continuous, uninterrupted and smooth manner in a direction of flow of the pressurized gas through the opening, as recited in independent claim 38.

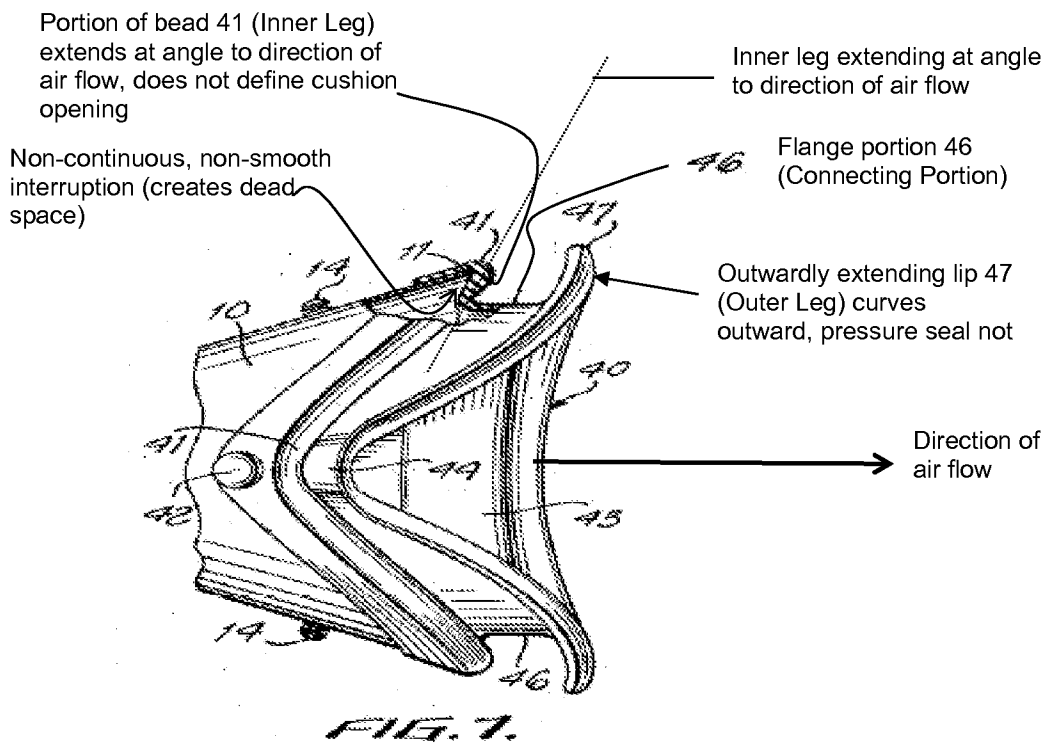
The Office Action admits that Gradon fails to describe the cross sectional configuration of the cushion. The Office Action asserts that Garelick discloses a cushion 40

having a U-shaped cross section defining a face-contacting surface, including an inner leg proximal to the frame at one end (11), and an outer leg (47) spaced away from the frame, the inner leg extending in a smooth, continuous and uninterrupted manner. The Office Action asserts that it would have been obvious to one of ordinary skill in the art to have replaced the Gradon cushion to have a same cross sectional configuration as taught by Garelick, in order to comfortably seal the mask to the user's face.

Based on this interpretation, Garelick does not teach at least the following claimed features:

First, as shown in Fig. 7 of Garelick (illustrated below), the "inner leg" of Garelick does not extend in the direction of air flow through the respirator, but instead extends at an angle to a direction of air flow through the respirator. Both the outer and inner legs of Garelick extend in a direction at a substantial angle to the direction of air flow through the respirator.

Second, Garelick does not disclose the inner leg defining an opening in the cushion, as recited in independent claims 24 and 38. The "inner leg" of Garelick is instead spaced back from and at an angle to the opening in the cushion. In contrast, the flange portion 46 defines the opening in the cushion of Garelick. For the inner leg of Garelick to define the opening in the cushion, the inner leg would need to be in the location of the flange 46.



Third, Garelick does not disclose the inner leg extending in a continuous, uninterrupted and smooth manner in a direction of flow of the pressurized gas through the opening. The inner leg includes a non-continuous, non-smooth interruption that creates dead space, as noted on the above figure. This non-continuous, non-smooth interruption is needed to properly align and seat the bead 41 to the mask. If the Examiner considers the inner leg to be only the portion extending substantially parallel to the lip 47 (outer leg), then the inner leg does not extend in the direction of the air flow. If the Examiner considers the inner leg to include the portion of the bead 41 extending at an obtuse angle in the area of reference numeral 11, then the inner leg (including the portion in the area of reference numeral 11) will not be in a u-shaped configuration (and will not extend in a continuous, uninterrupted and smooth manner in a direction of flow of the pressurized gas through the opening). Garelick's inner leg contains the sharp discontinuity that would inhibit air flow and perhaps create a pocket that would be prone to accumulate CO₂, which is undesirable. The mask of Garelick requires the discontinuity in the bead 41, so that the cushion will properly align to the frame and seat in the correct location, such that it would not be obvious to remove it or make it smooth.

For at least these reasons, independent claims 24 and 38, and claims 25-37 and 39-51 dependent therefrom, would not have been obvious over Gradon in view of Garelick.

Error #3 Gradon in view of Garelick do not teach an inner leg that extends to the opening (claims 33 and 47)

Claim 33 recites that the inner leg extends to the opening and claim 47 recites that the inner leg extends to the air flow opening. These features are not disclosed in Garelick as asserted in the Office Action. As noted above, the opening is defined by the flange portions 46 (asserted to be the connecting portion). The inner leg of Garelick is positioned upstream in the direction of airflow from the opening in the cushion. For the inner leg of Garelick to extend to the opening, it would need to be positioned in the location of flange 46.

For at least these reasons, dependent claims 33 and 47 would not have been obvious over Gradon in view of Garelick.

Error #4 Gradon in view of Garelick do not teach a connecting portion that has a generally convex shape (claims 35 and 49)

Claims 35 and 49 recite the cushion extending from the outer leg across the connecting portion and to the inner leg has a generally convex shape. In Garelick, at least the flange portion 46 (asserted to be the connecting portion) is not disclosed as having a generally convex shape. Instead, the flange 46 appears to be flat, as illustrated in at least Figs. 1 and 3-7.

As a result of the above, there is simply no support for the rejection of Applicants' claims. Applicants respectfully request that the Pre-Appeal Panel find that the application is allowed on the existing claims.